REMARKS

Applicant wishes to thank the Examiner for the attention accorded to the instant application, and respectfully requests reconsideration of the application in light of the following remarks.

Formal Matters

Claims 1-21 are currently pending in the application. Claim 1 is amended to correct informalities. No new matter has been added.

Rejection of Claims Under 35 U.S.C. §103

The Examiner has rejected Claims 1-5 and 9-15 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,755,715 to Stern et al., (hereinafter "Stern") in view of U.S. Patent No. 6,752,804 to Simpson (hereinafter "Simpson") and in further view of U.S. Patent No. 6,334,093 to More (hereinafter "More"). This rejection should be withdrawn based on the remarks herein.

Claim 1 recites a method for measuring temperature at a site within a patient during a medical procedure, the method comprising: *inter alia*, providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; placing the medical device within the patient and positioning the position sensor at the site; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; and providing a temperature measurement signal to the position sensor; measuring voltage at the position sensor; determining a resistance value at the position sensor based on the temperature measurement signal provided to the position sensor and the voltage at the position

sensor; and determining a temperature value at the position sensor based on the resistance value at the position sensor.

Claim 13 recites a method for adjusting for temperature sensitivity of a medical device having a position sensor, the method comprising: *inter alia*, providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; measuring voltage at the position sensor; determining a resistance value at the position sensor based on the measured voltage at the position sensor; determining a temperature value at the position sensor based on the resistance value; and determining a sensitivity at the position sensor based on the temperature value.

The claimed invention contemplates monitoring temperatures at a site within a patient, by determining a resistance value at a position sensor, which is used to accurately place a medical device to the site.

Stern is directed to an apparatus for ablating heart tissue using energy emitted from an energy source. Specifically, Stern discloses a temperature sensor (30), in the form of a bead thermistor, carried by the distal tip (16) of the catheter (14) for directly measuring a temperature (*see*, Col. 6, Lines 15-17):

> "The temperature control signal $T_{CONTROL}$ input is based upon the actual instantaneous temperature conditions sensed $T_{M(t)}$ by the sensing element 30."

Thus, Stern only teaches the application of a traditional temperature sensor for measuring a temperature at a site within a patient.

Additionally, Stern teaches that a temperature set curve is defined to allow thermal mapping (*see*, Col. 2, Lines 25-30):

> "In one embodiment, the temperature set curve includes a first region of temperature values over time that are below tissue ablating temperatures to allow thermal mapping, as well as a second region of temperature values over time that are at tissue ablating temperatures. This temperature set curve coordinates thermal mapping with tissue ablation".

However, nowhere does Stern teach or fairly suggest that the thermal mapping technique is used to determine or indicate the position of an ablation electrode. Thus, Applicant respectfully disagrees with the Examiner's allegation that the Stern "discloses thermal mapping and techniques which indicate the position of the medical device" (*see*, Page 3, Line 4-5 of the Official Action). Furthermore, the Examiner has acknowledged that Stern does not disclose the use of a position sensor.

Thus, Applicant respectfully submits that Stern fails to teach or suggest the steps of: providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; and determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system, as recited in Claims 1 and 13. In addition, Stern also fails to teach or suggest any of the steps, recited in Claims 1 and 13, associated with the position sensor, for example, the step of determining a resistance value at the position sensor based on measured voltage at the position sensor and determining a temperature value at the position sensor based on the resistance value.

The Examiner has relied on Simpson for the alleged teaching of the above-distinguishing features.

Simpson allegedly discloses a catheter having a plurality of electrodes, each with multiple thermal sensors attached and used to position the electrodes proximal to biological tissue of interest (see Page 3, Lines 4-6 of the Official Action).

However, Simpson teaches assessment of thermal sensor positions based on the thermal readings of the sensor. Simpson discloses at Col. 3, Lines 53-62 (cited by the Examiner):

> "Hence, those skilled in the art have recognized a need for providing an RF ablation system having a catheter with an electrode carrying multiple thermal sensors for providing temperature readings at a plurality of locations on the electrode and for presenting those readings in a manner which assists in the assessment of both electrode position and thermal sensor position relative to the ablation tissue. The need for automatic control of the energy level applied to an electrode, in view of the electrode and thermal sensor position assessment, has also been recognized". (emphasis added)

In view of the above recognized need, Simpson discloses an apparatus for determining the position of a plurality of thermal sensors relative to biological tissue undergoing the application of energy (Col. 4, Lines 6-8). Specifically, the apparatus includes a device for commonly carrying the thermal sensors; a catheter for carrying the device and positioning the device proximal the biological tissue; and a processor responsive to the thermal sensors for determining the temperature of each thermal sensor (Col. 4, Lines 9-13). The apparatus also includes a display responsive to the processor for providing a graphic representation of the temperature of each thermal sensor relative to the temperature of each of the other thermal sensors wherein the graphic representation is indicative of the proximity of the thermal sensors to the biological tissue (Co. 4, Lines 13-19).

By providing a graphic representation of the temperature of each thermal sensor relative to the temperature of each of the other thermal sensors that is indicative of the proximity of the thermal sensors to the biological tissue, the user is provided with additional

information that may aid in deciding whether to adjust the position or orientation of the device relative to the tissue and whether to adjust the applied electrical energy to the catheter's device during the application of therapy. Specifically, Simpson discloses that the graphic representation is in a form of a spread (132), which indicates the temperature disparity between two adjacent thermal sensors. Since a thermal sensor proximal to the tissue surface normally feeds back higher readings and a thermal sensor distal to the tissue surface normally feeds back lower readings, the approximate position of the device with respect to the surface of tissue can be estimated.

Furthermore, Simpson discloses the device (16) includes twelve band electrodes (32) arranged in a substantially linear array along the distal segment (34) of the catheter (30). Each band electrode has a thermal sensor (40) mounted to it. Each thermal sensor (40) provides a temperature signal, which is indicative of the temperature of the respective band electrode (32) at that sensor.

Thus, although Simpson teaches assisting in the assessment of both electrode position and thermal sensor position based on the thermal readings of the thermal sensor, Simpson does not disclose a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor, as recited in Claims 1 and 13 of the present application.

Furthermore, Simpson teaches assessing thermal sensor positions based on the thermal readings; in contrast, Claims 1 and 13 recite determining a temperature value at the position sensor based on the resistance value at the position sensor.

Accordingly, Simpson does not teach or suggest the steps of: providing a medical device having a position sensor for providing signals used in determining position

and/or orientation coordinates of the position sensor; and determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system, as recited in Claims 1 and 13. Also, Simpson fails to teach or suggest any of the steps, recited in Claims 1 and 13, associated with the position sensor, for example, the step of determining a resistance value at the position sensor based on measured voltage at the position sensor and determining a temperature value at the position sensor based on the resistance value. Stately differently, Simpson fails to remedy the underlying deficiencies of Stern.

More is relied on for the alleged teaching of applying a resistance drift compensation factor. Without acquiescing to the correctness of the Examiner's interpretation of More, Applicant respectfully submits that the alleged teaching of More does not remedy the underlying deficiencies of Stern and Simpson relative to independent Claims 1 and 13.

Thus, none of the cited references, namely Stern, Simpson and More, taken alone or in combination, teach or fairly suggest the combination of steps recited by Claims 1 and 13, from which all other claims depend ultimately.

Accordingly, withdrawal of the rejection of Claims 1-5 and 9-15 under 35 U.S.C. § 103(a) based on the hypothetical combination of Stern, Simpson and More is respectfully requested.

The Examiner has further rejected Claims 6-8 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stern in view of Simpson, More and U.S. Patent No. 5, 833,608 to Acker (hereinafter "Acker"). This rejection should be withdrawn based on the comments and remarks herein.

Claim 1, from which Claims 6-8 depend, is discussed above. Stern, Simpson and More are discussed above relative to Claim 1.

Acker is relied on to allegedly teach the additional limitations recited by Claims 6-8, such as AC magnetic field and temperature measurement signal. Without acquiescing to the correctness of the Examiner's interpretation of Acker, Applicant respectfully submits that Acker does not remedy the underlying deficiencies of Stern, Simpson and More relative to independent Claim 1.

Thus, the hypothetical combination of Stern, Simpson, More and Acker fails to teach or fairly suggest the combination of steps recited by Claim 1. Accordingly, withdrawal of the rejection of Claims 6-8 under 35 U.S.C. § 103(a) based on the hypothetical combination of Stern, Simpson, More and Acker is respectfully requested.

The Examiner has rejected Claims 16-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stern in view of Simpson, More and U.S. Patent No. 5, 638,418 to Douglas et al., (hereinafter "Douglas"). This rejection should be withdrawn based on the comments and remarks herein.

Claim 13, from which Claims 16-21 depend, is discussed above. Stern, Simpson and More are discussed above relative to Claim 13.

Douglas is relied on to allegedly teach the additional limitations recited by Claims 16-21, such as applying a resistance drift factor to the resistance value. Without acquiescing to the correctness of the Examiner's interpretation of Douglas, Applicant respectfully submits that Douglas does not remedy the underlying deficiencies of Stern, Simpson and More relative to independent Claim 13.

Thus, the hypothetical combination of Stern, Simpson, More and Douglas fails to teach or fairly suggest the combination of steps recited by Claim 13. Accordingly,

withdrawal of the rejection of Claims 16-21 under 35 U.S.C. § 103(a) based on the combination of Stern, Simpson, More and Douglas is respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

/Paul J. Esatto, Jr./

Paul J. Esatto, Jr.
Registration No. 30,749

Dated: September 24, 2010

Scully, Scott, Murphy & Presser, PC.
400 Garden City Plaza, Suite 300
Garden City, New York 11530
(516) 742-4343

PJE/KRV/HC/ech